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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/030,606	02/25/1998	JIANGCHUN XU	210121.428C3	7583

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SEED INTELLECTUAL PROPERTY LAW GROUP PLLC  
701 FIFTH AVE  
SUITE 6300  
SEATTLE, WA 98104-7092

EXAMINER

DAVIS, MINH TAM B

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 02/27/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/030,606

Applicant(s)

XU ET AL.

Examiner

MINH-TAM DAVIS

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM  
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 December 2001.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 23,24,29-36 and 41-46 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 23,24,35 and 36 is/are allowed.
- 6) ☒ Claim(s) 29-34 and 41-46 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_                      6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

The request filed on 12/04/01 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No: 09/030606 is acceptable and a CPA has been established. An action on the CPA follows.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant deletes claims 25-28, 37-40.

Accordingly, claims 23-24, 29-36, 41-46 are being examined.

Claims 23-24, 35-36 are free of prior art and are allowable.

The following are the remaining rejections.

### **REJECTION UNDER 35 USC 101, UTILITY**

Rejection under 35 USC 101 of claims 29-34, 41-46 pertaining to lack of specific utility remains for reasons already of record in paper No.21.

Applicant argues that the prior Declaration by Dr. R Houghton clearly shows that SEQ ID NO:172-175 and 177, which are variants of P703P are prostate-specific, expressing in prostate tumors and normal prostate tissues, but not significantly in any other normal tissues. Similarly, SEQ ID NO: 223 and 224 are prostate-specific. Thus for reasons similar to the reasons established for P501S or SEQ ID NO:110, the sequences of SEQ ID NO:172-175, 177, 223, 224 satisfy the utility requirement. Applicant asserts that the claimed sequences of SEQ ID NO:172-175, 177, 223, 224 could be used to detect prostate tumor cells in circulation, thus offering valuable

diagnostic and prognostic information about the presence in a subject of an invasive prostate tumor. Applicant further asserts that an important prognostic event during prostate cancer progression is the acquisition by tumor cells of the ability to become invasive, escape the site of the primary tumor and enter the circulation system, where the tumor cells can then potentially colonize distant organ sites. The presence of metastatic tumor cells that have entered the circulation and/or colonized organ sites distinct from the site of origin of the primary tumor generally results in less favorable prognosis than is the case when tumor cells are contained within a single non-invasive lesion in a subject.

Applicant's arguments set forth in paper No.25 have been considered but are not deemed to be persuasive for the following reasons:

It is noted that contrary to Applicant assertion, SEQ ID NO:110 is different from the claimed sequences of SEQ ID NO:172-175, 177, 223, 224 in that only SEQ ID No:110 has been detected as having a high level of expression in serum of patients with prostate cancer, as compared to normal healthy human, as indicated in the Declaration by Dr Houghton on 04/16/01.

It is unpredictable that using the claimed sequences of SEQ ID NO:172-175, 177, 223, 224, detection of the presence of prostate cells in circulation would be useful for diagnostic and prognostic information about the presence in a subject of an invasive prostate tumor, because Gelmini S et al, 2001, Clin Chem Lab Med, 39(5): 385-91, teach that circulating prostate cells can be detected in peripheral blood of patients with

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clinically localized or advanced prostate carcinoma. Thus, one of would not have expected that the presence of prostate cells in circulation would be useful for distinguishing between localized and advanced or metastasized prostate carcinoma.

Further, it is unpredictable that metastasized prostate cells still express the claimed sequences, because expression of a sequence could be lost during the progression toward metastasis. For example, Kibel, AS et al, 2000, J urol, 164(1): 192-6 teach that gene expression in the chromosomal region 12p12-13 is different in primary and metastatic cells, and that inactivation in the chromosome region 12p12-13 occurs prior to metastasis. Ren, C et al, 1998, Cancer Res, 58(6): 1285-90, teach a loss of expression of lysyl oxidase mRNA during progression to metastasis. Gingrich, JR et al, 1996, Cancer res, 56(18): 4096-4102 teach a loss of normal E-cadherin expression as primary tumors become less differentiated and metastasize.

Thus in view of the above, one would not have expected that the claimed sequences are useful for diagnostic and prognostic information about the presence in a subject of an invasive prostate tumor.

Further, the claimed polynucleotides are organ specific, i.e. specific to prostate, and thus their utilities based solely on prostate specific property, such as treating or detecting prostate cancer are not specific, and are shared by other unrelated prostate specific molecules.

**REJECTION UNDER 35 USC 112, FIRST PARAGRAPH, ENABLEMENT**

Rejection under 35 USC 112, first of of claims 29-34, 41-46 pertaining to lack of support from a specific utility remains for reasons already of record in paper No.21.

The same arguments and answers from 101 rejection above apply here as well.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 703-305-2008. The examiner can normally be reached on 9:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ANTHONY CAPUTA can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0916.

  
ANTHONY C. CAPUTA  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600

MINH TAM DAVIS

February 15, 2002